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camptothecin, clonazepam, cyclosporine A, diazepam, dicumarol, digitoxine, dipyrimidamole, disopyramide, flunitrazepam, gemfibrozil, ketochlorin, ketoconazole, miconazole, niflumic acid, oxazepam, phenobarbital, phenytoin, progesterone, propofol, ritonavir, sulfinpyrazone, suprofen, tacrolimus, tamoxifen, taxonoid, testosterone, tirilazad, trioxsalen, valproic acid and warfarin; and

iii) a plasma protein selected from the group consisting of human serum albumin, immunoglobulin, glycoprotein, interferon and interleukin, non-covalently bound to the therapeutically active drug.

96. (New) The pharmaceutical formulation of claim 95, wherein the taxonoid further consists of a taxonoid of the general formula I - in the formula;  
R<sup>1</sup> represents tert. butyl-oxy-carboxylic acid amide or benzoyl amide,  
R<sup>2</sup> represents hydrogen or any acyl group and of a plasma protein fraction.
97. (New) The pharmaceutical formulation of claim 95, wherein the therapeutically active drug is paclitaxel and the plasma protein is selected from the group consisting of human serum albumin, recombinant human plasma albumin and  $\gamma$ -globulin.
98. (New) The pharmaceutical formulation of claim 95, wherein the therapeutically active drug is amphotericin B and the plasma protein is selected from the group consisting of human serum albumin, recombinant human plasma albumin and  $\gamma$ -globulin.
99. (New) The pharmaceutical formulation according to claim 95, wherein the therapeutically active drug is camptothecin and the plasma protein is selected from the group consisting of human serum albumin, recombinant human plasma albumin and  $\gamma$ -globulin.
100. (New) The pharmaceutical formulation of claim 95, wherein the therapeutically active drug is carbamazepin and the plasma protein is selected from the group consisting of human serum albumin, recombinant human plasma albumin and  $\gamma$ -globulin.
101. (New) The pharmaceutical formulation of claim 95, wherein the therapeutically active drug is cyclosporin A and the plasma protein is selected from the group consisting of human serum albumin, recombinant human plasma albumin and  $\gamma$ -globulin.
102. (New) The pharmaceutical formulation of claim 95, wherein the therapeutically active drug is propofol and the plasma protein is selected from the group consisting of human serum albumin, recombinant human plasma albumin and  $\gamma$ -globulin.

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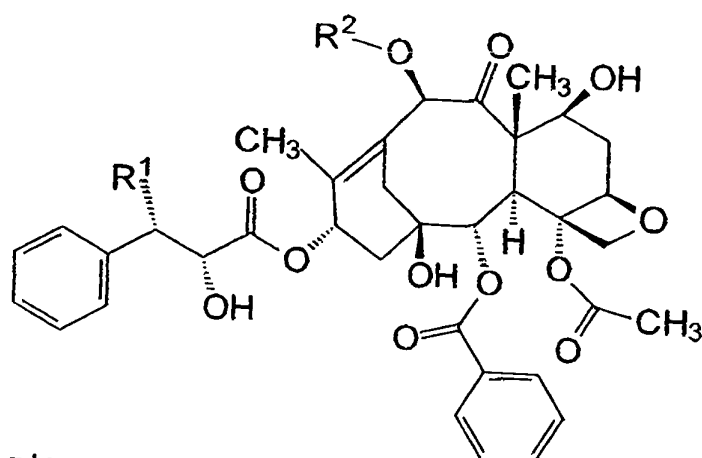
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103. (New) The pharmaceutical formulation of claim 95, wherein the therapeutically active drug has an aqueous solubility of less than  $1 \times 10^{-6}$  M.
104. (New) The pharmaceutical composition of claim 95, wherein the therapeutically active drug has an aqueous solubility of less than  $1 \times 10^{-6}$  M.
105. (New) The pharmaceutical composition of claim 95, further comprising an additive from the group consisting of a stabilizer, and a protein aggregation controller.
106. (New) The pharmaceutical composition of claim 95, wherein the molar ratio of the therapeutically active drug to plasma protein is within the range of 1 : 0.05 to 1 : 100.
107. (New) The pharmaceutical composition of claim 95, wherein the molar ratio of the therapeutically active drug to plasma protein is within the range of 1 : 0.1 to 1 : 50.
108. (New) The pharmaceutical composition of claim 95, wherein the plasma protein is derived from a human.
109. (New) The pharmaceutical composition of claim 95, wherein the plasma protein is derived from an animal other than human.
110. (New) The pharmaceutical composition of claim 95, wherein the plasma protein is a natural plasma protein or a recombinant plasma protein.
111. (New) The pharmaceutical composition of claim 95, wherein the plasma protein is selected from the group consisting of human serum albumin, animal serum albumin, recombinant human serum albumin, recombinant animal serum albumin,  $\gamma$ -globulin, and recombinant  $\gamma$ -globulin.
112. (New) The pharmaceutical composition of claim 95, wherein the plasma protein is selected from a group consisting of immunoglobulin, glycoprotein, interferon, interleukin, and recombinant immunoglobulin, glycoprotein, interferon, and interleukin.
113. (New) The pharmaceutical composition of claim 95, wherein the therapeutically active drug is selected from the group consisting of a cytostatic, an antibiotic, a vitamin, an anti-inflammatory, an analgesic, an antiviral, an anticonvulsant, an immunosuppressant, an antiepileptic, an anxiolytic, a hypnotic, an antifungal agent, an anticoagulant, a lipid peroxidase inhibitor, a coronary vasodilator, an antiarrhythmic agent, a cardiotonic, an uricosuric, an antithrombotic, a steroid hormone (progesterone, androgen, testosterone)

and a photosensitizer; and the plasma protein is selected from the group consisting of natural and recombinant serum albumin and  $\gamma$ -globulin.

114. (New) The pharmaceutical composition of claim 95, wherein the therapeutically active drug is selected from the group consisting of a cytostatic, an antibiotic, a vitamin, an anti-inflammatory, an analgesic, an antiviral, an anticonvulsant, an immunosuppressant, an antiepileptic, an anxiolytic, a hypnotic, an antifungal agent, an anticoagulant, a lipid peroxidase inhibitor, a coronary vasodilator, an antiarrhythmic agent, a cardiotonic, an uricosuric, an antithrombotic, a steroid hormone (progesterone, androgen, testosterone) and a photosensitizer; and the plasma protein is selected from the group consisting of immunoglobulin, glycoprotein, interferon, and interleukin and recombinant immunoglobulin, glycoprotein, interferon, interleukin.
115. (New) The pharmaceutical composition of claim 95, wherein the therapeutically active drug is selected from the group consisting of amphotericin B, an adriamycin analogue, apazone, azathioprine, bromazepam, camptothecin, carbamazepine, clonazepam, cyclosporine A, diazepam, dicumarol, digitoxine, dipyridamole, disopyramide, flunitrazepam, gemfibrozil, ketochlorin, xetoconazole, miconazole, niflumic acid, oxazepam, phenobarbital, phenytoin, progesterone, propofol, ritonavir, sulfinpyrazone, suprofen, tacrolimus, tamoxifen, taxonoid, testosterone, tirilazad, trioxsalen, valproic acid, warfarin; and the plasma protein is selected from the group consisting of natural and recombinant serum albumin and  $\gamma$ -globulin.
116. (New) The pharmaceutical composition of claim 95, wherein the therapeutically active drug is selected from the group consisting of amphotericin B, an adriamycin analogue, apazone, azathioprine, bromazepam, camptothecin, carbamazepine, clonazepam, cyclosporine A, diazepam, dicumarol, digitoxine, dipyridamole, disopyramide, flunitrazepam, gemfibrozil, ketochlorin, xetoconazole, miconazole, niflumic acid, oxazepam, phenobarbital, phenytoin, progesterone, propofol, ritonavir, sulfinpyrazone, suprofen, tacrolimus, tamoxifen, taxonoid, testosterone, tirilazad, trioxsalen, valproic acid, warfarin; and the plasma protein is selected from the group consisting of immunoglobulin, glycoprotein, interferon, and interleukin and recombinant immunoglobulin, glycoprotein, interferon, and interleukin.
117. (New) The pharmaceutical composition of claim 95, wherein the taxonoid is having the following formula:



wherein R<sup>1</sup> is tertiary butyl-oxy-carboxylic acid amide or benzoyl amide,  
 R<sup>2</sup> is hydrogen or an acyl group.

118. (New) The pharmaceutical composition of claim 117, wherein the acyl group is an acetyl group.
119. (New) The pharmaceutical composition of claim 111, wherein the therapeutically active drug is paclitaxel.
120. (New) The pharmaceutical composition of claim 112, wherein the therapeutically active drug is paclitaxel.
121. (New) The pharmaceutical composition of claim 111, wherein the therapeutically active drug is amphotericin B.
122. (New) The pharmaceutical composition of claim 112, wherein the therapeutically active drug is amphotericin B.
123. (New) The pharmaceutical composition of claim 111, wherein the therapeutically active drug is gemfibrozil.
124. (New) The pharmaceutical composition of claim 112, wherein the therapeutically active drug is gemfibrozil.
125. (New) The pharmaceutical composition of claim 111, wherein the therapeutically active drug is miconazole.

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126. (New) The pharmaceutical composition of claim 112, wherein the therapeutically active drug is miconazole.
127. (New) The pharmaceutical composition of claim 111, wherein the therapeutically active drug is propofol.
128. (New) The pharmaceutical composition of claim 112, wherein the therapeutically active drug is propofol.
129. (New) The pharmaceutical composition of claim 111, wherein the therapeutically active drug is tamoxifen.
130. (New) The pharmaceutical composition of claim 112, wherein the therapeutically active drug is tamoxifen.
131. (New) The pharmaceutical composition of claim 111, wherein the therapeutically active drug is ritonavir.
132. (New) The pharmaceutical composition of claim 112, wherein the therapeutically active drug is ritonavir.
133. (New) The pharmaceutical composition of claim 111, wherein the therapeutically active drug is tacrolimus.
134. (New) The pharmaceutical composition of claim 112, wherein the therapeutically active drug is tacrolimus.
135. (New) The pharmaceutical composition of claim 111, wherein the therapeutically active drug is tirilazad.
136. (New) The pharmaceutical composition of claim 112, wherein the therapeutically active drug is tirilazad.
137. (New) The pharmaceutical composition of claim 111, wherein the therapeutically active drug is trioxsalen.
138. (New) The pharmaceutical composition of claim 112, wherein the therapeutically active drug is trioxsalen.
139. (New) The pharmaceutical composition of claim 105, wherein the additive is selected

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from the group consisting of sodium chloride, a buffer, a poly-alcohol and a water-soluble sugar derivative.

140. (New) The pharmaceutical composition of claim 139, wherein the poly-alcohol is selected from the group consisting of glycerol, mannitol, sorbitol, and dulcitol.

**Status of the claims:**

Claims 30-37, 42-90 and 93-94 are pending.

Applicants respectfully traverse the rejections and request reconsideration and withdrawal of all rejections in view of the Remarks set forth below. It is believed that this amendment does not raise new issues that would require further consideration and search, and also does not present new matter. It is also believed and respectfully submitted that this amendment simply to comply with the 35 U.S.C. § 112 requirement expressly set forth in the previous Office actions. Applicants further submit that the amendment places this application in better form for appeal by materially reducing or simplifying the issues for appeal.

**REMARKS**

Applicants acknowledge the examiner's confirmation that i) claims 1-23 and 38-41 were cancelled; ii) claims 24-29 were withdrawn and iii) claims 91-92 were withdrawn from consideration. Applicants further acknowledge the examiner's withdrawal of the rejections regarding i) claims 1-9 under 35 U.S.C. § 102(b) or alternatively, 103(a); and ii) claims 1-10 under 35 U.S.C. § 102(e) as being anticipated by Desai.

**Rejection of Claims 30-37 Under 35 U.S.C. 112, First Paragraph**

Claims 30-37 stand rejected under 35 U.S.C. § 112 first paragraph as allegedly not providing enablement for composition other than paclitaxel and albumin. New claims 95-102 are now added to replace claims 30-37.